



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/943,458	08/30/2001	Dwight D. Weller	50450-8038.US00	9454
22918	7590	10/25/2006	EXAMINER	
PERKINS COIE LLP P.O. BOX 2168 MENLO PARK, CA 94026			KIM, YOUNG J	
			ART UNIT	PAPER NUMBER
			1637	
DATE MAILED: 10/25/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary**Application No.**

09/943,458

Applicant(s)

WELLER ET AL.

Examiner

Young J. Kim

Art Unit

1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 August 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3, 5-11 and 19-27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 5, 6, 10 and 19-27 is/are rejected.
- 7) ☒ Claim(s) 7-9 and 11 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The present Office Action is responsive to the Amendment received on August 10, 2006.

Preliminary Remark

Claims 4 and 12-18 are canceled.

Claims 1-3, 5-11, and 19-27 are pending and are under prosecution herein.

Claim Rejections - 35 USC § 112

The rejection of claims 1-3, 5-11, 15-17, 19-27¹ under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter, made in the Office Action mailed on February 15, 2006 is withdrawn in view of the Amendment received on August 10, 2006.

Claim Rejections - 35 USC § 102

The rejection of claims 1-3, 5, 6, 10, 15-17, 19, 20, 23, and 24 under 35 U.S.C. 102(b) as being anticipated by Fuchs et al. (WO 97/12995, published April 10, 1997), made in the Office Action mailed on February 15, 2006 is withdrawn in view of the arguments presented in the Amendment received on August 10, 2006.

Particularly, Applicants' argument stating that the instant claims require that a single, fully charged nucleic acid or nucleic acid analog be hybridized to a plurality (i.e., more than one), or all of the substantially uncharged oligomeric analyte molecules (see page 7, Response) is found convincing.

¹ Previous Office Action mailed on February 15, 2006 contained a typographical error, stating the claims 1-27 were rejected. This, in fact, is an error, as claims 4, 12-14, and 18 were canceled.

Art Unit: 1637

Rejection, New Grounds

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 5, 6, 10, 19, 20, 23, 24, 26, and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Bruice et al. (U.S. Patent No. 5,686,242, issued November 11, 1997).

Bruice et al. disclose a method of calibrating various 2'-O-Methyl oligonucleotides (or substantially uncharged oligomeric analyte molecules for binding to ras RNA target sequence (or a fully charged nucleic acid), wherein the artisans employ the following 2-O-Methyl oligonucleotides:

UUGCCCACAC

UUGCCCACAU

UUGCUCACAC

CUGCCCACAU; and

CUGUUUACAU (see column 22, lines 26-30)

The artisans state that the above oligonucleotides were designed to bind ras 47-mer stem/loop RNA sequence (column 22, lines 14-16).

Their calibration method, the artisans provide a mixture of calibration 2'-O-methyl oligonucleotides with said ras RNA sample (column 22, lines 41-46; lines 14-15), wherein the duplexes formed therebetween are eluted through an FPLC column, wherein the separation of the duplexes are determined based on their retention times (column 22, lines 44-46), thereby clearly anticipating claims 1, 2, 5, 6, 10, 19, 20, 23, 24, 26, and 27.

Art Unit: 1637

With regard to claim 3, the claim further defines one of the members of the Markush group recited in claim 2, but does not actively require that the method employ this member. As Bruice et al. employ a 2'-O-methyl oligonucleotide for a "selected sequence," that is, a portion on ras 47-mer, the limitation of claim 3 is fully met.

Therefore, Bruice et al. clearly anticipate the invention as claimed.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 21, 22, and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bruice et al. (U.S. Patent No. 5,686,242, issued November 11, 1997) in view of Ecker et al. (U.S. Patent No. 5,986,053, issued November 16, 1999).

The teachings of Bruice et al. have already been discussed above.

Bruice et al. do not explicitly teach that the DNA be labeled instead of the PNAs.

Bruice et al. do not explicitly employ morpholino oligomers.

Ecker et al. disclose a gel-shift motility assay, which involves hybridization of PNA molecules to DNA molecules, thereby forming PNA:DNA duplexes, wherein the DNA molecules are labeled (column 14, lines 38-41; column 35, lines 23-29).

Art Unit: 1637

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Bruice et al. with the teachings of Ecker et al., thereby arriving at the claimed invention for the following reasons.

The case for *prima facie* obviousness is established based on whether one of ordinary skill in the art would have had a reasonable expectation of success at conducting the method of Bruice et al. for DNA molecules rather than RNA molecules.

Given the fact that oligonucleotide:nucleic acid hybridization assay have been well-established, and in view of the fact that one of ordinary skill in the art would have recognized that hybridization reactions involving RNAs can also be replicated at DNA level, and in view of the fact that Ecker et al. demonstrates the stability of an uncharged oligonucleotide formed between DNA which withstands charge bearing separation, one of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of success at arriving at the invention as claimed.

With regard to the use of morpholino oligonucleotides, one of ordinary skill in the art at the time the invention was made would have been motivated to employ any of the well-known oligomers which are known to be resistant to enzyme degradation, such as 2'OMe as well as PMOs, given the fact that Bruice et al. contemplate therapy employing 2'OMe oligomers (column 5, lines 55-67; column 6, lines 12-25). One of ordinary skill in the art at the time the invention was made would have recognized that oligomers commonly employed in therapies, such as PMOs would have also been useful in their method.

Therefore, for the above reasons, the invention as claimed is *prima facie* obvious over the cited references.

Art Unit: 1637

Conclusion

No claims are allowed.

Claims 7-9 and 11 are objected to for being dependent on a rejected base claim.

Inquiries

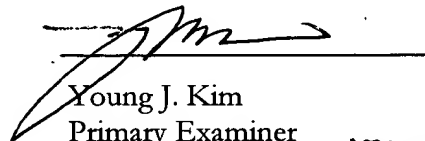
Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Young J. Kim whose telephone number is (571) 272-0785. The Examiner is on flex-time schedule and can best be reached from 8:30 a.m. to 4:30 p.m (M-W and F). The Examiner can also be reached via e-mail to Young.Kim@uspto.gov. However, the office cannot guarantee security through the e-mail system nor should official papers be transmitted through this route.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. Gary Benzion, can be reached at (571) 272-0782.

Papers related to this application may be submitted to Art Unit 1637 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If applicant does submit a paper by FAX, the original copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office. All official documents must be sent

Art Unit: 1637

to the Official Tech Center Fax number: (571) 273-8300. For Unofficial documents, faxes can be sent directly to the Examiner at (571) 273-0785. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-1600.



Young J. Kim

Primary Examiner

Art Unit 1637

10/20/2006

**YOUNG J. KIM
PRIMARY EXAMINER**

YJK